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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,504

05/16/2006

Christian Paulus

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DICKE, BILLIG & CZAJA

FIFTH STREET TOWERS

100 SOUTH FIFTH STREET, SUITE 2250

MINNEAPOLIS, MN 55402

EXAMINER

KAUR, GURPREET

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,504	Applicant(s) PAULUS, CHRISTIAN	
	Examiner GURPREET KAUR	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-32 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/25/2008, 3/20/2008, 12/11/2007</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claim 19 is objected to because of the following informalities: claim 19 states “one a group comprising of a semiconductor material, glass, plastic, and ceramic,” it should state “one a group consist of a semiconductor material, glass, plastic, and/or ceramic.” Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Madou et al. (U.S. Pat. No. 4,874,500).

Regarding claim 29, Madou et al. teaches a biosensor circuit (see col. 12, lines 20-23) comprising:

forming an integrated circuit (48) in a substrate (12) (see col. 12, lines 20-23);
an integrated reference electrode (reference electrode) in (connected) the integrated circuit (48) on the substrate (see figure 1);

forming a core (silver layer) of an integrated reference electrode (reference electrode) by depositing silver material as metal on the substrate (12) (see col. 18, lines 16-29 and figure 2) and surrounding the core made up of silver material by a sheath (layer) made up of sparingly soluble salt of the silver (AgCl) to form integrated reference

Art Unit: 1795

electrode (reference electrode) (see col. 18, lines 16-29, see col. 16, lines 42-44 and figure 2);

composite membrane such as enzyme based membrane can also be disposed in the well (see col. 7, lines 31-34), therefore sensor array (see figure 9) includes biological molecules (enzyme based membrane);

electrically coupling (connecting) the integrated circuit (48) to the core of the integrated reference electrode (see col. 12, lines 50-53 and figure 4 and 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madou et al. (U.S. Pat. No. 4,874,500) in view of Hill et al. (U.S. Pat. No. 5,727,548).

Regarding claim 13, Madou et al. teaches a method for producing a biosensor circuit (see col. 12, lines 20-23) comprising:

forming an integrated circuit (48) in a substrate (12) (see col. 12, lines 20-23);

forming a core (silver layer) of an integrated reference electrode (reference electrode) by depositing silver material as metal on the substrate (12) (see col. 18, lines 16-29 and figure 2);

surrounding the core made up of silver material by a sheath (layer) made up of sparingly soluble salt of the silver (AgCl) to form integrated reference electrode (reference electrode) (see col. 18, lines 16-29, see col. 16, lines 42-44 and figure 2)

electrically coupling (connecting) the integrated circuit (48) to the core (silver layer) of the integrated reference electrode (see col. 12, lines 50-53 and figures 4 and 7).

Madou et al. also indicates that the composite membrane; such as an enzyme based membrane, can also be disposed in the well (see col. 7, lines 31-34) which is comprised of electrodes. Furthermore, Madou et al. teaches that the array of sensing cells (working electrode) can be provided on the substrate (see col. 13, lines 232-35).

Madou et al. does not teach that the applying biological molecules by printing on the sensor array and effecting the printing of silver material on the substrate and printing of the biological molecules on the sensor array in the same work step.

Art Unit: 1795

However, Hill et al. teaches a method of producing a device comprising electrodes and permanent circuitry components wherein the biological molecules (enzyme containing layer 43) are screen printed on the sensing cell (active electrode) (see col. 12, lines 58-64 and figure 7), hence the active electrode is activated. Furthermore, Hill et al. also teaches that reference electrode is also screen printed on the substrate (see col. 12, lines 40-43). Therefore, it would be obvious to person of ordinary skill in the art to screen print both reference electrode and biological molecules in the same work step.

Furthermore, the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (see MPEP § 2144.04). Moreover, the use of a known technique to improve similar devices (methods or products) in the same way is likely to be obvious. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143, C.).

Advantage to method of Hill et al. is that it is amenable to high volume automation and is of high reproducibility (see col. 12, lines 49-50).

Therefore it would be obvious to person of ordinary skill in the art at the time of invention to incorporate the method of Hill et al. with the method of Madou et al. because advantage of such a method that it is amenable to high volume automation and is of high reproducibility.

Regarding claims 16 and 17, Madou et al. teaches that silver chloride is the salt of the metal (silver) which is produced by chlorinating the core made up of silver by chemical method (see col. 18, lines 18-29).

Regarding claim 18, Madou et al. indicates that the integrated circuit (48) is configured in a manner such that it process signals generated from the reference electrode (see col. 12, lines 23-26).

Regarding claim 19, Madou et al. teaches that the substrate (12) is made up of semiconductor material (see col. 4, lines 37-38).

Claims 14, 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madou et al. (U.S. Pat. No. 4,874,500) in view of Hill et al. (U.S. Pat. No. 5,727,548) as applied to claim 13 above, and further in view of Saito et al. (U.S. Pat. No. 6,021,339).

Regarding claim 14, Madou et al. teaches a coupling structure (palladium layer) is layered underneath the silver/silver chloride layer for formation of the reference electrode and the conductor is used to electrically couple the integrated circuit (48) with the reference electrode which comprises the silver core. (see col. 18, lines 18-24, col.12, lines 49-51 and figures 6 and 7).

Madou et al. does not indicate that the coupling structure is used to electrically couple the integrated circuit with core of the reference electrode.

Art Unit: 1795

However, Saito et al. teaches a sensor wherein the reference electrode is made by layering the coupling structure (titanium and platinum layer) underneath the core (silver layer) on the substrate and a lead is also formed on the same substrate to connect the reference electrode to current detecting circuit (see col. 7, lines 14-19 and figures 4A-C and 6). Saito et al. indicates that coupling structure (titanium and platinum layers) are formed for improved contactivity (see col. 7, lines 17-18), therefore it would be obvious that coupling structure (titanium and platinum layers) is used to couple the core (silver layer) with the current detecting circuit.

Therefore it would have been obvious to person of ordinary skill in the art at the time of invention to incorporate the coupling structure of the Saito et al. with the Madou et al. device to for improved contactivity between the reference electrode and the integrated circuit.

Regarding claim 15, Saito et al. teaches that the coupling structure (titanium and platinum layer) is underneath the core (silver layer) (see col. 7, lines 17-19), therefore the core (silver layer) covers the coupling structure.

Regarding claim 20, Saito et al. teaches that the coupling structure is formed from platinum (see col. 7, lines 17-18).

Claims 21 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madou et al. (U.S. Pat. No. 4,874,500) in view of Yoshikawa (English machine translation of JP 11238733,) and Hill et al. (U.S. Pat. No. 5,727,548).

Regarding claim 21, Madou et al. teaches method for producing a biosensor circuit (see col. 12, lines 20-23) comprising:

forming an integrated circuit (48) in a substrate (12) (see col. 12, lines 20-23);

forming a core (silver layer) of an integrated reference electrode (reference electrode) by depositing silver material as metal on the substrate (12) (see col. 18, lines 16-29 and figure 2);

surrounding the core made up of silver material by a sheath (layer) made up of sparingly soluble salt of the silver (AgCl) to form integrated reference electrode (reference electrode) (see col. 18, lines 16-29, see col. 16, lines 42-44 and figure 2)

electrically coupling (connecting) the integrated circuit (48) to the core of the integrated reference electrode (see col. 12, lines 50-53 and figure 4 and 7).

Madou et al. also indicates that the composite membrane; such as an enzyme based membrane, can also be disposed in the well (see col. 7, lines 31-34), which is comprised of electrodes. Furthermore, Madou et al. teaches that the array of sensing cells (working electrode) can be provided on the substrate (see col. 13, lines 232-35).

Madou et al. does not teach that the reference electrode is made by printing silver salt material on the substrate and chemically reducing the silver salt material to form silver and Madou et al. also does not teach about applying biological molecules by

Art Unit: 1795

printing on sensor array and effecting the printing of silver material on the substrate and printing of the biological molecules on the sensor array in the same work step.

However, Yoshikawa et al. teaches method of making electronic device (see paragraph 001) wherein the silver layer (9a) is deposited by applying silver salt material (ammonia based silver nitrate) on the substrate (2) and chemically reducing the silver salt material to form silver (see paragraph 18). Yoshikawa et al. further indicates that such a method provides less heat to the substrate during formation of the silver layer (see paragraph 32)

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to incorporate the Yoshikawa et al. method of forming silver layer with the Madou et al. method to impart less heat to substrate to prevent damage to the substrate.

Furthermore, Hill et al. teaches a method of producing a device comprising electrodes and permanent circuitry components wherein the biological molecules (enzyme containing layer 43) are screen printed on the active electrode (see col. 12, lines 58-64 and figure 7), hence the active electrode is activated. Furthermore, Hill et al. also teaches that reference electrode is also screen printed on the substrate (see col. 12, lines 40-43). Therefore, it would be obvious to person of ordinary skill in the art to screen print both reference electrode and biological molecules in the same work step.

Art Unit: 1795

Furthermore, the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (see MPEP § 2144.04). Moreover, the use of a known technique to improve similar devices (methods or products) in the same way is likely to be obvious. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143, C.).

Advantage to method of Hill et al. is that it is amenable to high volume automation and is of high reproducibility (see col. 12, lines 49-50)

Therefore it would be obvious to person of ordinary skill in the art at the time of invention to incorporate the method of Hill et al. with the method of Madou et al. because advantage of such a method that it is amenable to high volume automation and is of high reproducibility.

Regarding claims 24 and 25, Madou et al. teaches that silver chloride is the salt of the metal (silver) which is produced by chlorinating the core made up of silver by chemical method (see col. 18, lines 18-29).

Regarding claim 26, Madou et al. indicates that the integrated circuit (48) is configured in a manner such that it process signals generated from the reference electrode (see col. 12, lines 23-26).

Regarding claim 27, Madou et al. teaches that the substrate (12) is made up of semiconductor material (see col. 4, lines 37-38).

Claims 22, 23 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madou et al. (U.S. Pat. No. 4,874,500) in view of Yoshikawa (English machine translation of JP 11238733,) and Hill et al. (U.S. Pat. No. 5,727,548) as applied to claim 21 above, and further in view of Saito et al. (U.S. Pat. No. 6,021,339).

Regarding claim 22, Madou et al. teaches a coupling structure (palladium layer) is layered underneath the silver/silver chloride layer for formation of the reference electrode and the conductor is used to electrically couple the integrated circuit (48) with the reference electrode which comprises the silver core. (see col. 18, lines 18-24, col.12, lines 49-51 and figures 6 and 7).

Madou et al. does not indicate that the coupling structure is used to electrically couple the integrated circuit with core of the reference electrode.

However, Saito et al. teaches a sensor wherein the reference electrode is made by layering the coupling structure (titanium and platinum layer) underneath the core (silver layer) on the substrate and a lead is also formed on the same substrate to connect the reference electrode to current detecting circuit (see col. 7, lines 14-19 and figures 4A-C and 6). Saito et al. indicates that coupling structure (titanium and platinum layers) are formed for improved contactivity (see col. 7, lines 17-18), therefore it would be obvious that coupling structure (titanium and platinum layers) is used to couple the core (silver layer) with the current detecting circuit.

Therefore it would have been obvious to person of ordinary skill in the art at the time of invention to incorporate the coupling structure of the Saito et al. with the Madou et al. device to for improved contactivity between the reference electrode and the integrated circuit.

Regarding claim 23, Saito et al. teaches that the coupling structure (titanium and platinum layer) is underneath the core (silver layer) (see col. 7, lines 17-19), therefore the core (silver layer) covers the coupling structure.

Regarding claim 28, Saito et al. teaches that the coupling structure is formed from platinum (see col. 7, lines 17-18).

Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madou et al. (U.S. Pat. No. 4,874,500) in view of Hill et al. (U.S. Pat. No. 5,727,548).

Regarding claims 30-32, Madou et al. also indicates that the composite membrane; such as an enzyme based membrane, can also be disposed in the well (see col. 7, lines 31-34), which is comprised of electrodes. Furthermore, Madou et al. teaches that the array of sensing cells (working electrode) can be provided on the substrate (see col. 13, lines 232-35).

Madou et al. does not teach that the applying biological molecules by printing on sensor array and effecting the printing of silver material on the substrate and printing of the biological molecules on the sensor array in the same work step.

However, Hill et al. teaches a method of producing a device comprising electrodes and permanent circuitry components wherein the biological molecules (enzyme containing layer 43) are screen printed on the active electrode (see col. 12, lines 58-64 and figure 7), hence the active electrode is activated. Furthermore, Hill et al. also teaches that reference electrode is also screen printed on the substrate (see col. 12, lines 40-43). Therefore, it would be obvious to person of ordinary skill in the art to screen print both reference electrode and biological molecules in the same work step.

Furthermore, the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (see MPEP § 2144.04). Moreover, the use of a known technique to improve similar devices (methods or products) in the same way is likely to be obvious. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143, C.).

Advantage to method of Hill et al. is that it is amenable to high volume automation and is of high reproducibility (see col. 12, lines 49-50)

Therefore it would be obvious to person of ordinary skill in the art at the time of invention to incorporate the method of Hill et al. with the method of Madou et al. because advantage of such a method that it is amenable to high volume automation and is of high reproducibility.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GURPREET KAUR whose telephone number is (571)270-7895. The examiner can normally be reached on Monday-Friday (Alternate Friday Off), 8:00-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571)272-1263. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. K./
Examiner, Art Unit 1795

Application/Control Number: 10/528,504

Page 15

Art Unit: 1795

/Brian J. Sines/

Supervisory Patent Examiner, Art Unit 1795